



California Medical Device Recall Information



Recall Name

Acclarent, Inc. Recalls The Inspira AIR Balloon Dilation System Due to Possible Malfunction

Recall Date	Product Description	Recalling Firm	Recall Reason
1/31/12	Inspira AIR Balloon Dilation System, size 18x40mm	Acclarent, Inc. , Menlo Park, CA	<i>Potential for balloon to not deflate or deflate slowly</i>
Recall Class	Product Identification	Distribution	Affected Dates
I	Inspira AIR Balloon Dilation System, size 18x40mm Product Code: <u>BC 1840A</u> Product Labels	CA , Nationwide	March 2011 to June 2011

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm295488.htm>

http://www.acclarent.com/media/files/pdfs/Acclarent_Inspira_Letter.pdf